

EXHIBIT L

Konstantin Walmsley, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC. : Master File
PELVIC REPAIR SYSTEM : No.
PRODUCTS LIABILITY : 2:12-MD-02327
LITIGATION :
: MDL NO. 2327
THIS DOCUMENT RELATES : JOSEPH R. GOODWIN
TO THE FOLLOWING CASES : U.S. DISTRICT JUDGE
IN WAVE 2 OF MDL 200: :
JOANNE PHILLIPS : CASE NO.
v. : 2:12-cv-02489
ETHICON, INC., et al. :
:

- - -

August 17, 2016

- - -

Expert deposition of
KONSTANTIN WALMSLEY, M.D., taken pursuant
to notice, was held at Courtyard Marriott
West Orange, 8 Rooney Circle, West
Orange, New Jersey, beginning at 12:42
p.m., on the above date, before Kimberly
A. Cahill, a Federally Approved
Registered Merit Reporter and Notary
Public.

- - -

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

Konstantin Walmsley, M.D.

Page 2

1 APPEARANCES:

2

3 MOTLEY RICE LLC

BY: HAYLEIGH T. STEWART SANTRA, ESQUIRE

4 28 Bridgeside Boulevard

Mt. Pleasant, South Carolina 29464

5 (843) 216-9373

hstewart@motleyrice.com

6 Representing the Plaintiffs

7

BUTLER SNOW LLP

8 BY: ASHLEY NADER STUBBS, ESQUIRE

Suite 1400

9 1020 Highland Colony Parkway

Ridgeland, Mississippi 39157

10 (601) 948-5711

ashley.stubbs@butlersnow.com

11 Representing the Defendants Johnson &
Johnson and Ethicon

12

13

14

15

16

- - -

17

18

19

20

21

22

23

24

Konstantin Walmsley, M.D.

Page 3

1 - - -
 2 I N D E X
 3 - - -

4
 5 Testimony of: KONSTANTIN WALMSLEY, M.D.
 6 By Ms. Stubbs 6
 By Ms. Santra 88

7
 8 - - -
 9 E X H I B I T S
 10 - - -

NO.	DESCRIPTION	PAGE
13	Walmsley Notice of	14
14	(Phillips)- Deposition of	
	1 Konstantin	
	Walmsley, M.D.	
16	Walmsley Rule 26 Expert	16
17	(Phillips)- Report of	
	2 Konstantin	
	Walmsley, MD	
18	Walmsley 11/20/15 Curriculum	17
19	(Phillips)- Vitae of Konstantin	
	3 Walmsley	
20	Walmsley Document Entitled	17
21	(Phillips)- "Materials	
	4 Reviewed"	
22	Walmsley 6/17/16 Encounter	21
23	(Phillips)- Summary for Joanne	
	5 Phillips	
24	Walmsley Invoice for	22

Konstantin Walmsley, M.D.

Page 4

1	(Phillips)-	Phillips Case	
2	6	Review	
3	Walmsley	6/16 AUGS and SUFU	36
4	(Phillips)-	Position Statement	
5	7		
6	Walmsley	1/10/05 Operative	66
7	(Phillips)-	Report for Joanne	
8	8	M. Phillips,	
9		PHILLIPSJ_UTMC_MDR	
10		00021 through	
11		PHILLIPSJ_UTMC_MDR	
12		00023	
13	Walmsley	Twenty Pages of	69
14	(Phillips)-	Medical Records	
15	9	Beginning with	
16		12/13/05 Visit to	
17		Dr. Narula,	
18		PHILLIPSJ_LAFHC_MDR	
19		00056	
20			
21			
22			
23			
24			

Konstantin Walmsley, M.D.

Page 6

1 - - -

2 KONSTANTIN WALMSLEY, M.D.,

3 after having been duly sworn, was

4 examined and testified as follows:

5 - - -

6 EXAMINATION

7 - - -

8 BY MS. STUBBS:

9 Q. Dr. Walmsley, we've met
10 before, but again, for the record, my
11 name is Ashley Stubbs and I'm here on
12 behalf of Ethicon and Johnson & Johnson.

13 Do you understand that we're
14 taking your deposition today in the
15 Joanne Phillips matter?

16 A. I do.

17 Q. And you've been retained by
18 the Motley Rice firm to render opinions
19 about the injuries Ms. Phillips is
20 claiming as a result of the TVT implant;
21 is that correct?

22 A. That's correct.

23 Q. I just want to make sure I
24 have an accurate list of the other cases

Konstantin Walmsley, M.D.

Page 7

1 that you've been deposed in that involve
2 Ethicon products.

3 A. Certainly.

4 Q. So I was going to run
5 through those, and tell me if I miss any.

6 A. Okay. Certainly.

7 Q. I have that you were deposed
8 in June of 2016 in the Martin case?

9 A. Yes, ma'am.

10 Q. And then also that month in
11 the Bailey case.

12 A. Yes, that's correct.

13 Q. And then same, June 2016, in
14 the Manor case?

15 A. Yes.

16 Q. And then in the Pridmore
17 case?

18 A. Yes.

19 Q. Then in the Lindberg case?

20 A. That's correct.

21 Q. It was a general deposition,
22 I believe?

23 A. Yeah, that's correct.

24 Q. And then the Sherry Fox

Konstantin Walmsley, M.D.

Page 8

1 matter?

2 A. Yes.

3 Q. And then the Ridgley,

4 R-I-D-G-L-E-Y?

5 A. The Ridgley matter, yes.

6 Q. Ridgley.

7 Barbee or Barbee, were you

8 deposed --

9 A. Barbee, yes, that was just
10 recently, yes.

11 Q. And then I deposed you in
12 the McIntyre case; is that correct?

13 A. Yes, ma'am.

14 Q. And then you were also
15 deposed in the Vanbuskirk case?

16 A. Yes.

17 Q. Javins? Javins?

18 A. Correct.

19 Q. Barr?

20 A. Correct.

21 Q. Garcia?

22 A. Yes.

23 Q. And then were you deposed
24 last week in the Ward and Baker cases?

Konstantin Walmsley, M.D.

Page 9

1 A. Yes.

2 Q. And then we're here today on
3 Phillips and I believe you have another
4 deposition taken in the Birt case; is
5 that correct?

6 A. B-I-R-T, yes.

7 Q. Any other cases that you've
8 been deposed in involving Ethicon
9 devices?

10 A. Yes.

11 Q. Okay. What are those names?

12 A. This is a case from 2010,
13 Gonzalez verse Ethicon. That relates to
14 a dysfunctional Ethicon stapler that
15 resulted in complications.

16 Q. So that wasn't a mesh
17 device; is that correct?

18 A. No, ma'am, no.

19 Q. Any other Ethicon cases that
20 we haven't discussed?

21 A. No.

22 Q. And then you've also served
23 as an expert witness for the plaintiffs
24 in other mesh cases involving devices not

Konstantin Walmsley, M.D.

Page 10

1 manufactured by Ethicon; is that correct?

2 A. Yes.

3 Q. And do those -- who are
4 those manufacturers?

5 A. Those manufacturers include
6 Bard, Boston Scientific, AMS. I believe
7 that's it.

8 Q. And in all of the cases
9 where you testified or been retained to
10 render opinions about a synthetic mesh
11 device, were those cases where you were
12 retained by the plaintiff?

13 A. In the pelvic mesh-related
14 arena, yes.

15 Q. And in all of those cases,
16 was it your opinion that the device
17 implanted in the plaintiff caused their
18 injuries?

19 A. To some degree, yes.

20 Q. And in those cases where you
21 served as an expert in synthetic mesh
22 device cases, did you also opine in all
23 of those cases that the warnings were
24 inadequate?

Konstantin Walmsley, M.D.

Page 11

1 A. No.

2 Q. Has there ever been a case
3 where you said the warnings were
4 adequate?

5 A. No.

6 Q. Okay.

7 A. There are certain instances
8 earlier on when I was retained in these
9 matters that I didn't comment on the IFU.
10 To my knowledge, I don't recall
11 commenting on the IFU, for example, in
12 the Martinez case, which was Martinez
13 versus AMS in March of 2014.

14 But certainly over time,
15 that has become an opinion of mine.

16 Q. When you were retained and
17 asked to render your opinion in any
18 synthetic mesh case about the IFU, was it
19 always your opinion that that IFU was
20 inadequate to warn the physician of the
21 risk claimed in the case?

22 A. In many instances, yes.

23 Q. Was there ever a case where
24 you didn't -- where you were asked to

Konstantin Walmsley, M.D.

Page 12

1 render an opinion as to the warnings and
2 didn't render that opinion?

3 A. I mean, the only instance in
4 which that happened were in cases where I
5 vetted those cases and felt, on behalf of
6 the attorneys who asked me to review the
7 case, that there weren't any issues
8 related to the mesh product.

9 Q. In all the cases where you
10 were deposed in, if in any of those cases
11 you were asked to render an opinion about
12 the IFU, just in the cases you were
13 deposed in, was it your opinion that the
14 IFU was inadequate?

15 A. That would be correct.

16 Q. What did you do to prepare
17 for your deposition today, Dr. Walmsley?

18 A. I had a brief discussion
19 with counsel prior to coming in the room.
20 I refreshed my memory as it relates to my
21 report and the medical records.

22 I also additionally reviewed
23 deposition of Dr. Kim and also a report
24 by a Dr. Shoemaker.

Konstantin Walmsley, M.D.

Page 13

1 MS. SANTRA: Off the record.

2 - - -

3 (A discussion off the record
4 occurred.)

5 - - -

6 MS. STUBBS: Back on.

7 BY MS. STUBBS:

8 Q. Doctor, we were discussing
9 what you did in preparation for your
10 deposition and off the record, Ms.
11 Stewart told me that she was going to
12 send me a link of the documents you
13 reviewed, so we won't mark that as an
14 exhibit, but we'll just note for the
15 record that that's being supplied by
16 counsel.

17 But if you could, tell me
18 the documents you reviewed in order to
19 prepare your report and opinions in this
20 case.

21 A. Certainly. So my report
22 came along with a reliance list, which
23 contains about two and a half pages of
24 reference articles. There's also

Konstantin Walmsley, M.D.

Page 14

1 mentions made in the reliance list as to
2 my reviewing of the current IFU, patient
3 brochures, applicable depositions, the
4 list of complaints, if you will, and I
5 believe some other -- some other -- some
6 other documents as well.

7 MS. STUBBS: Okay.

8 Let me just go ahead and
9 mark a few documents as exhibits
10 and then we'll be able to look at
11 your reliance list together.

12 THE WITNESS: Certainly.

13 - - -

14 (Deposition Exhibit No.
15 Walmsley (Phillips)-1, Notice of
16 Deposition of Konstantin Walmsley,
17 M.D., was marked for
18 identification.)

19 - - -

20 BY MS. STUBBS:

21 Q. So, first, I'm going to hand
22 you just the deposition notice.

23 A. Yes.

24 Q. And are you familiar with

Konstantin Walmsley, M.D.

Page 15

1 this notice?

2 A. I am.

3 Q. And this is what requested
4 you to appear today in the Phillips case;
5 correct?

6 A. Yes, ma'am.

7 Q. And as part of that, we
8 asked you to bring certain documents with
9 you; is that correct?

10 A. Uh-hum.

11 Q. And off the record, counsel
12 provided me with the invoice for this
13 case, for your charges to date, and
14 there's some other documents we requested
15 and I'm going to walk through those.

16 But first I want to ask you,
17 have you reviewed any Ethicon company
18 documents to date?

19 MS. SANTRA: Object to form.

20 MS. STUBBS: For the
21 Phillips matter.

22 THE WITNESS: I mean, with
23 the exception of the TVT IFU and
24 having seen a brochure, I've not.

Konstantin Walmsley, M.D.

Page 16

1 BY MS. STUBBS:

2 Q. You haven't reviewed any
3 internal company e-mails in this matter;
4 is that correct?

5 MS. SANTRA: Object to form.

6 THE WITNESS: I have not.

7 - - -

8 (Deposition Exhibit No.
9 Walmsley (Phillips)-2, Rule 26
10 Expert Report of Konstantin
11 Walmsley, MD, was marked for
12 identification.)

13 - - -

14 BY MS. STUBBS:

15 Q. I'm going to hand you what I
16 marked as Exhibit 2 -- it's a copy of
17 your report -- and just ask you, is that
18 a correct copy of your report in the
19 Joanne Phillips matter?

20 A. Yes, it is.

21 Q. And does this report contain
22 all of your opinions in the Phillips
23 case?

24 A. Yes, it does.

Konstantin Walmsley, M.D.

Page 17

1 - - -

2 (Deposition Exhibit No.
3 Walmsley (Phillips)-3, 11/20/15
4 Curriculum Vitae of Konstantin
5 Walmsley, was marked for
6 identification.)

7 - - -

8 BY MS. STUBBS:

9 Q. Then I'm going to hand you
10 what I marked as Exhibit 3 and just ask
11 you to verify that this is an updated
12 copy of your C.V.

13 A. Yes.

14 - - -

15 (Deposition Exhibit No.
16 Walmsley (Phillips)-4, Document
17 Entitled "Materials Reviewed", was
18 marked for identification.)

19 - - -

20 BY MS. STUBBS:

21 Q. And then as Exhibit 4, is
22 this the reliance list that you referred
23 to earlier as far as the materials
24 reviewed in formulating your opinions in

Konstantin Walmsley, M.D.

Page 18

1 the Phillips case?

2 A. That's correct.

3 Q. And so then let's look at
4 Exhibit 4, the materials reviewed. It
5 states that you looked at depositions of
6 medical providers. Is that the
7 deposition of Dr. Kim?

8 A. Yes.

9 Q. Did you review any other
10 depositions of any other treaters in this
11 case?

12 A. I did not.

13 Q. Did you also review the
14 deposition testimony of the plaintiff?

15 A. I did.

16 Q. And then medical and billing
17 records, did you review all medical
18 records provided to you by counsel in
19 this case?

20 A. I did.

21 Q. Have you reviewed any
22 additional records since drafting your
23 report?

24 A. The only other additional

Konstantin Walmsley, M.D.

Page 19

1 record that I reviewed in her behalf was
2 a expert report by a Dr. Shoemaker.

3 Hayleigh, did you send me
4 additional records on her? I don't quite
5 recollect seeing them. I just -- that's
6 why I'm checking.

7 MS. STUBBS: Oh, please.

8 Thank you.

9 THE WITNESS: Yeah, yeah.

10 BY MS. STUBBS:

11 Q. And when you refer to Dr.
12 Shoemaker, that's the expert on behalf of
13 Ethicon; is that correct?

14 A. That's correct.

15 Q. And did his report in any
16 way change any of your opinions in your
17 report that was served?

18 A. No, ma'am.

19 MS. STUBBS: Hayleigh, while
20 you look for that, I'm just going
21 to keep going.

22 MS. SANTRA: Sure. That's
23 fine.

24 BY MS. STUBBS:

Konstantin Walmsley, M.D.

Page 20

1 Q. Next, you list instructions
2 for use. Did you review the TVT IFU that
3 was in place in January of 2005 when Ms.
4 Phillips had her implant?

5 A. I did.

6 Q. And did you review any other
7 TVT IFUs?

8 A. Specific to this case, no,
9 but I have a whole dossier of IFUs.

10 Q. But as far as your opinions
11 in this case regarding the warnings, do
12 they pertain solely to the IFU in place
13 at the time of Ms. Phillips' implant?

14 A. Yes.

15 Q. And then you also list the
16 patient brochure. Is that the patient
17 brochure that was in use in January of
18 2005?

19 A. Correct.

20 Q. Do you have any opinions
21 about the adequacy of the patient
22 brochure in this matter?

23 A. I don't.

24 Q. Then you also reviewed the

Konstantin Walmsley, M.D.

Page 21

1 plaintiff fact sheet; is that correct?

2 A. Yes, I did.

3 Q. And then you list numerous
4 articles that you reviewed. Anything
5 else that's not contained in this
6 reliance list that you reviewed in this
7 matter?

8 A. No.

9 - - -

10 (Deposition Exhibit No.
11 Walmsley (Phillips)-5, 6/17/16
12 Encounter Summary for Joanne
13 Phillips, was marked for
14 identification.)

15 - - -

16 BY MS. STUBBS:

17 Q. I'm going to show you next
18 what I've marked as Exhibit 5. This is
19 what we have as your IME record for Ms.
20 Phillips.

21 Did you take any notes
22 during the IME or is everything reflected
23 in this document that pertains to Ms.
24 Phillips' IME?

Konstantin Walmsley, M.D.

Page 22

1 A. I did not take any notes.

2 Really everything that I documented and
3 recorded during my IME is present in the
4 report.

5 Q. When you say report, are you
6 referring to the IME or the expert
7 report?

8 A. The IME.

9 Q. And we'll walk through that
10 in further detail later, but it is your
11 testimony today that any information
12 taken down by you would be contained --
13 during the IME would be contained in that
14 document; is that correct?

15 A. Yes.

16 - - -

17 (Deposition Exhibit No.
18 Walmsley (Phillips)-6, Invoice for
19 Phillips Case Review, was marked
20 for identification.)

21 - - -

22 BY MS. STUBBS:

23 Q. And then I'm going to show
24 you what I've marked as Exhibit 6. This

Konstantin Walmsley, M.D.

Page 23

1 is the invoice that counsel provided us
2 with before the deposition began for your
3 fees in the Phillips case.

4 Can you tell me for the
5 record how much you've been paid in this
6 case?

7 A. \$5,575.

8 Q. And what do those charges
9 include?

10 A. They include the review of
11 the medical records and depositions, as
12 well as the preparation of the report.

13 Q. Do you recall when you were
14 first retained in this case?

15 A. It would have been in the
16 latter part of May to early June.

17 Q. Of this year?

18 A. 2016, yes.

19 Q. And how long did it take you
20 to formulate your opinions in this case?

21 A. Roughly eight to nine hours.

22 Q. And your opinions were based
23 on the review of the documents we've
24 discussed?

Konstantin Walmsley, M.D.

Page 24

1 A. In part, yes.

2 Q. And then also of your
3 physical exam of the plaintiff?

4 A. And my IME, yes.

5 Q. Have you spoken with any of
6 Ms. Phillips' treating physicians?

7 A. No.

8 Q. And on how many occasions
9 have you met Ms. Phillips?

10 A. Only once.

11 Q. And was that during the IME?

12 A. Yes.

13 Q. What is your hourly rate?

14 A. \$500 an hour.

15 Q. And does that include -- is
16 that a flat rate for any of your work or
17 is there a different rate for testimony,
18 for example?

19 A. It's more or less the same.
20 For out-of-town court appearances where a
21 full day is taken, it's a
22 five-thousand-dollar rate unless the time
23 spent exceeds eight hours.

24 Q. Did you personally draft

Konstantin Walmsley, M.D.

Page 25

1 your report in this matter?

2 A. I did.

3 Q. Doctor, I believe that
4 defense expert Dr. Shoemaker at the time
5 of issuing the report hadn't conducted an
6 IME yet, but I know that that is in the
7 works -- Hayleigh, I'm not sure when
8 that's scheduled -- but is that something
9 that you would want to review and
10 consider whether or not you need to
11 supplement your opinions based on that if
12 an IME is done?

13 A. Certainly, yes.

14 Q. Before we get into your
15 opinions in this case and the IME, I'd
16 like to talk to you a little bit about
17 the condition that Ms. Phillips had with
18 regard to incontinence.

19 In your practice, what
20 percentage of your practice is dedicated
21 to treating women with incontinence?

22 A. Probably 20 percent. It's a
23 guess.

24 Q. And would that include women

Konstantin Walmsley, M.D.

Page 26

1 with stress urinary incontinence as well
2 as urge incontinence?

3 A. Yes.

4 Q. And would you agree that the
5 device TVT is indicated to treat stress,
6 not urge, incontinence?

7 A. That's correct.

8 Q. And would you agree that Ms.
9 Phillips had mixed incontinence, meaning
10 a stress component and an urge component?

11 A. You're talking about at the
12 time of her initial implant?

13 Q. At the time of her implant,
14 yes.

15 A. She had mixed urinary
16 incontinence.

17 Q. Would you agree that stress
18 and urge incontinence greatly affect a
19 woman's quality of life?

20 A. Yes.

21 Q. And would you agree that a
22 surgery using a mesh device to treat SUI
23 is an elective procedure?

24 A. Yes.

Konstantin Walmsley, M.D.

Page 27

1 Q. It's not a life-threatening
2 condition.

3 A. Only quality of
4 life-threatening, as I often talk to
5 patients about.

6 Q. How do you see in your
7 practice incontinence affect your
8 patients' lives?

9 A. Well, it's well-known that
10 incontinence is a quality-of-life
11 condition and there have been numerous
12 studies looking at quality of life in
13 women with incontinence.

14 And there's no question that
15 it affects quality of life in multiple
16 ways, not only because of the condition
17 itself and the fact that having
18 incontinence can increase risk of skin
19 breakdown, urinary tract infections, but
20 it also has social and psychological
21 impacts, for example, maybe not being
22 involved or active in the same things you
23 might have been before, whether it be
24 exercise or certain social situations,

Konstantin Walmsley, M.D.

Page 28

1 wearing black, for example, to kind of
2 hide incontinence.

3 There have been studies that
4 have correlated depression with urinary
5 incontinence, so it's certainly impactful
6 on multiple levels.

7 Q. Would you agree that it's
8 important to have both surgical and
9 nonsurgical treatment options available
10 to women for the treatment of
11 incontinence?

12 A. Yes.

13 Q. And would you agree that
14 there are risks associated with any
15 surgical treatment of stress urinary
16 incontinence, whether that is with or
17 without mesh?

18 A. Yes.

19 Q. Would you agree that the
20 risk of scar formation -- scar tissue
21 formation -- is a risk associated with
22 any surgery to treat SUI whether that's
23 with or without mesh?

24 A. Not completely, but in part,

Konstantin Walmsley, M.D.

Page 29

1 yes.

2 Q. What part do you disagree
3 with?

4 A. Any surgery can create
5 scarring; however, surgery involving the
6 use of pelvic mesh creates a greater
7 degree of scarring.

8 Q. I know one of your opinions
9 -- and we'll get into it in further
10 detail -- is regarding alternative
11 treatment options as opposed to using a
12 mid-urethral sling like TVT; is that
13 correct?

14 A. Correct.

15 Q. And you propose using a
16 fascial sling; is that correct?

17 A. An autologous fascial sling,
18 yes.

19 Q. And that's where actual
20 human tissue is used to repair or to
21 treat stress urinary incontinence; is
22 that correct?

23 A. That's an instance where
24 instead of creating the support to the

Konstantin Walmsley, M.D.

Page 30

1 urethra with a synthetic piece of
2 polypropylene mesh, one actually uses
3 what's called fascia, which is a
4 connective tissue layer that can mimic or
5 provide a similar support.

6 Q. And would you agree that
7 that alternative procedure does not
8 involve the use of a medical device?

9 MS. SANTRA: Object to form.

10 THE WITNESS: Correct.

11 Other than suture material to
12 suture the sling in place, that
13 would be correct.

14 BY MS. STUBBS:

15 Q. And that's because you're
16 using the actual tissue to provide
17 support; correct?

18 A. Yes.

19 Q. And would you agree that
20 there are risks associated with that
21 procedure?

22 A. I would.

23 Q. And would you agree that
24 that is a longer operating time?

Konstantin Walmsley, M.D.

Page 31

1 A. This is true.

2 Q. And does that risk -- does
3 that surgery, using human tissue as
4 opposed to a polypropylene-based mesh,
5 does that surgery present the risk of
6 scar formation?

7 A. Yeah.

8 Q. Can that surgery result in
9 dyspareunia?

10 MS. SANTRA: Object to form.

11 THE WITNESS: To some
12 degree, yes.

13 BY MS. STUBBS:

14 Q. Can that surgery result in
15 pelvic pain?

16 A. Once again, to some degree,
17 yes.

18 Q. Currently, you said 20
19 percent of your practice is dedicated to
20 treating women with incontinence; is that
21 correct?

22 A. That's correct.

23 Q. Of those patients that you
24 treat, how many of them would you say,

Konstantin Walmsley, M.D.

Page 32

1 percentage-wise, do you ultimately
2 perform surgery on?

3 A. Probably about 20 to 30
4 percent.

5 Q. And when you don't perform a
6 procedure to treat the incontinence, are
7 you using medication?

8 A. Typically, medications or
9 lifestyle/behavioral modifications, in
10 addition to physical therapy.

11 Q. And in this particular case,
12 Ms. Phillips, before having the TVT
13 implant, she tried alternative forms of
14 therapy including Detrol LA; is that
15 correct?

16 A. She did try medications for
17 her condition, yes.

18 Q. And based on the records I
19 reviewed, it looked like the Detrol was
20 actually helping; is that correct?

21 A. It was helping with her
22 urgency and urgency urinary incontinence,
23 yes.

24 Q. But not the stress; is that

Konstantin Walmsley, M.D.

Page 33

1 correct?

2 A. That's correct.

3 Q. And, ultimately, she elected
4 to go forward with the TVT procedure to
5 treat her stress incontinence; correct?

6 A. Yes.

7 Q. And the Detrol to your --
8 strike that.

9 Based on your review of the
10 records, did the Detrol have any impact
11 on her stress incontinence?

12 A. Not that I could conclude
13 from my evaluation of the records, no.

14 Q. Do you disagree with Dr.
15 Kim's decision in any way to implant TVT
16 in Ms. Phillips in 2005?

17 A. I do not.

18 Q. Do you agree that she was an
19 appropriate candidate for that device
20 based on her presentation of symptoms in
21 January 2005?

22 A. I do.

23 Q. Going back to your opinion
24 regarding alternative forms of treatment

Konstantin Walmsley, M.D.

Page 34

1 and, instead of using a sling or a
2 polypropylene-based sling, using human
3 tissue to repair it, would you agree that
4 that surgery using human tissue also
5 presents the risk of recurrence of
6 urinary problems?

7 A. Yes.

8 Q. Does it present the risk of
9 infection?

10 A. Yes.

11 Q. Do you agree that
12 mid-urethral slings are a -- within the
13 standard of care currently for the
14 treatment of stress urinary incontinence?

15 A. Yes.

16 Q. Do you currently implant any
17 mid-urethral slings as a treatment option
18 for your patients suffering from stress
19 urinary incontinence?

20 A. I do.

21 Q. And is that -- what device
22 is that that you use?

23 A. I'm using the Coloplast ARIS
24 device.

Konstantin Walmsley, M.D.

Page 35

1 Q. And is that a
2 polypropylene-based sling?

3 A. It is.

4 Q. And you would agree that TVT
5 is a polypropylene-based sling; correct?

6 A. Yes.

7 Q. Why do you choose to use the
8 sling you use as opposed to TVT?

9 A. A lot of times when we
10 examine devices and kits, obviously
11 besides an analysis of related
12 literature, discussions with key opinion
13 leaders, to a large degree, the -- you
14 can get a lot of information from
15 palpating and examining mesh.

16 One of the issues that I
17 find appealing about the Coloplast sling
18 is, it tends to have less elasticity, so
19 as a result, the rate of contraction is
20 less, which essentially means when I
21 place the sling, I don't have to
22 necessarily be concerned as much about
23 the way that sling will change over time
24 as it relates to contraction.

Konstantin Walmsley, M.D.

Page 36

1 Q. Okay.

2 A. So I'm still placing the
3 sling in a tension-free fashion, but I'm
4 less concerned about how the contraction
5 of the sling will affect patients'
6 voiding function long term.

7 Q. Did you see any evidence of
8 contraction of Ms. Phillips' sling when
9 you examined her?

10 A. I did not.

11 MS. STUBBS: Doctor, I know
12 we've walked through this position
13 statement in other cases, so I'm
14 not going to go through it in any
15 great detail, but I want to show
16 you what I've marked as Exhibit 7,
17 the AUGS and SUFU position
18 statement that was updated in
19 2016.

20 - - -

21 (Deposition Exhibit No.
22 Walmsley (Phillips)-7, 6/16 AUGS
23 and SUFU Position Statement, was
24 marked for identification.)

Konstantin Walmsley, M.D.

Page 37

1 - - -

2 BY MS. STUBBS:

3 Q. Are you familiar with this
4 position statement?

5 A. I am.

6 Q. Are you a member of AUGS or
7 SUFU?

8 A. I'm not.

9 Q. Would you agree that those
10 are reputable medical organizations?

11 A. I'm not very in tune with
12 the specific nature of these
13 organizations. That being said, I have
14 colleagues who are good doctors who are
15 members of the organizations, so I would
16 have to conjecture that they would be
17 reputable organizations.

18 Q. And are you not a member of
19 these organizations because you're not a
20 urogynecologist?

21 A. No.

22 Q. Okay.

23 A. The AUGS society is geared
24 towards urogynecologists, but the SUFU

Konstantin Walmsley, M.D.

Page 38

1 society is open to urogynecologists as
2 well as physicians such as myself who
3 have received fellowship training in
4 female urology.

5 Q. And why are you not a member
6 of that organization?

7 A. You know, I'm so busy
8 clinically that joining the organization
9 has never been something that has been
10 compelling or meaningful to me, not to
11 say that I wouldn't appreciate the
12 opportunity to be a member, but it's just
13 never, you know, appealed to me just
14 because I'm so busy clinically as it is.

15 Q. If you would look with me,
16 this position statement that I've marked
17 as Exhibit 7 discusses the use of
18 mid-urethral slings for stress urinary
19 incontinence; correct?

20 A. Yes.

21 Q. Would you turn with me to
22 the second page and the point number 3?
23 In bold, it states: "Polypropylene mesh
24 mid-urethral slings are a standard of

Konstantin Walmsley, M.D.

Page 39

1 care for the surgical treatment of SUI
2 and represent a great advance in the
3 treatment of this condition for our
4 patients."

5 Did I read that correctly?

6 A. You did.

7 Q. Do you disagree with that
8 statement?

9 MS. SANTRA: Object to form.

10 THE WITNESS: The only, you
11 know, adjective I would disagree
12 with is "great." I think it's
13 obviously an advance in the
14 treatment of this condition. It
15 has advantages, but it also has
16 disadvantages.

17 And, I mean, I think to be
18 fair, if we try to identify
19 reasons for this statement being
20 put forth, you know, in part, the
21 position statement has been put
22 forth because the use of slings,
23 there has been some controversy
24 created obviously with the current

Konstantin Walmsley, M.D.

Page 40

1 environment that we're in
2 regarding slings.

3 So inasmuch as I think it's
4 an advance, I would argue the
5 point that it's a great advance
6 simply because I think there are
7 pros and cons to using slings.

8 Certainly if you compare the
9 use of polypropylene slings for
10 stress urinary incontinence, it's
11 still used, perhaps not as
12 commonly as it was three or four
13 years ago, for example, but it's
14 still used, which I think is
15 reflective of the fact that
16 there's an advance.

17 BY MS. STUBBS:

18 Q. Would you agree that in the
19 past three or four years, the litigation
20 environment surrounding the pelvic mesh
21 products, in particular the mid-urethral
22 slings, has had an effect on doctors
23 using those devices?

24 MS. SANTRA: Object to form.

Konstantin Walmsley, M.D.

Page 41

1 THE WITNESS: Well, I would
2 expand the answer pool to say it's
3 both affected doctors and
4 patients, but yes.

5 BY MS. STUBBS:

6 Q. Do you agree that -- you
7 said there are advantages and
8 disadvantages to using a mid-urethral
9 sling; correct?

10 A. Yes.

11 Q. Would you agree that there
12 are disadvantages as well as advantages
13 to using -- to any surgical treatment to
14 treat SUI?

15 A. I think that's fair, yes.

16 Q. In that same section,
17 section 3, if you go down a few lines,
18 the sentence starting "MUS is associated"
19 --

20 A. Uh-hum.

21 Q. -- it says, "MUS is
22 associated with less pain, shorter
23 hospitalization, faster return to usual
24 activities, and reduced costs as compared

Konstantin Walmsley, M.D.

Page 42

1 to historic options that have been used
2 to treat SUI over the past century."

3 Did I read that correctly?

4 A. You did.

5 Q. Do you disagree or agree
6 with that statement?

7 A. I would agree with every
8 single comment made there, but I'm not as
9 privy to the reduced costs analysis. And
10 the reason I'm not is because the slings
11 and the devices carry costs. The fact
12 that patients are not in the hospital as
13 long would diminish costs. Complication
14 rates probably would create costs.

15 So I'm not privy to the
16 analysis that points out reduced costs.

17 Q. But other than that
18 statement -- that portion of the
19 statement, you agree with the statement
20 that I just read?

21 A. This is true.

22 Q. I'd like to go to your
23 report and let's discuss opinion number
24 1. And this opinion is regarding the IFU

Konstantin Walmsley, M.D.

Page 43

1 in place at the time of Ms. Phillips'
2 implant; correct?

3 A. Yes.

4 Q. And it is your opinion that
5 the IFU in place in January of 2005 was
6 not sufficient to enable informed consent
7 of Ms. Phillips; is that correct?

8 A. Yes.

9 Q. What do you contend should
10 have been in the IFU that wasn't?

11 A. Well, firstly --

12 MS. SANTRA: Object to the
13 form.

14 THE WITNESS: -- there's
15 terminology in the IFU that would
16 indicate a clinician to believe
17 that the response to pelvic mesh
18 is a temporary response.

19 And I quote from one of the
20 adverse reaction statements from
21 the IFU in 2005, quote:
22 Transitory local irritation at the
23 wound site and a transitory
24 foreign body response may occur.

Konstantin Walmsley, M.D.

Page 44

1 This response could result in
2 extrusion, erosion, fistula
3 formation and inflammation,
4 unquote.

5 Quite frankly, I think
6 that's a misleading statement
7 because those words imply
8 temporary and we know that the
9 reaction to mesh, the foreign body
10 reaction, the inflammatory
11 response, is a chronic one.

12 And in addition, there are
13 additional adverse reactions
14 and/or risks within the use of
15 suburethral slings that aren't
16 mentioned in the IFU, for example,
17 pelvic pain and dyspareunia.

18 And what's important to know
19 is that inasmuch as
20 antiincontinence procedures for
21 SUI can create these potential
22 complications, the nature of them
23 is different. For example,
24 dyspareunia can be much more

Konstantin Walmsley, M.D.

Page 45

1 difficult to manage in the
2 mesh-based mid-urethral sling
3 setting than, for example, in an
4 autologous fascial sling.

5 So besides, for example,
6 pelvic pain and dyspareunia, it's
7 not only the provision of those
8 potential adverse events; it's the
9 fact that there's no language or
10 context to those potential adverse
11 events that speaks to the
12 difficulty unique to those adverse
13 events in the mesh arena.

14 BY MS. STUBBS:

15 Q. Let's start with your first
16 opinion regarding the transitory response
17 language.

18 A. Okay.

19 Q. Did you see any evidence
20 when you examined Ms. Phillips of a
21 chronic inflammatory response or foreign
22 body response?

23 MS. SANTRA: Object to form.

24 THE WITNESS: Well, I think

Konstantin Walmsley, M.D.

Page 46

1 that's a difficult question to
2 answer because, to be fair, those
3 specific descriptive terms that
4 we've just been using are really
5 histopathological types of terms.

6 What you can appreciate and
7 what I did appreciate on Ms.
8 Phillips' exam is the presence of
9 a scar plate and tenderness
10 related to my exam. Those are
11 reflective of an inflammatory
12 process.

13 But to be fair, those
14 terminologies are probably more
15 aptly used in a histopathological
16 type of context.

17 BY MS. STUBBS:

18 Q. Would you agree that in
19 order to render an opinion to a
20 reasonable degree of medical certainty
21 that Ms. Phillips had a chronic
22 inflammatory response, you would need
23 pathology?

24 MS. SANTRA: Object to form.

Konstantin Walmsley, M.D.

Page 47

1 THE WITNESS: Not
2 necessarily, because certainly on
3 clinical exam, if one appreciates
4 indurated and/or scarred tissue,
5 for example, around a mesh sling,
6 especially in the presence of
7 tenderness, in most often -- in
8 most instances, within a
9 reasonable degree of medical
10 certainty, that defines or
11 supports the presence of an
12 inflammatory response.

13 BY MS. STUBBS:

14 Q. Would you agree that an
15 inflammatory response is a known risk of
16 implanting any device in the pelvic
17 space?

18 MS. SANTRA: Object to form.

19 THE WITNESS: Well,
20 certainly, for a synthetic mesh
21 product, that inflammatory
22 response will be a chronic one;
23 whereas, with nonsynthetic-based
24 or biological graft material, for

Konstantin Walmsley, M.D.

Page 48

1 example, the response is a
2 self-limited one. There is an
3 inflammatory response. There
4 obviously is some degree of
5 scarring, as there is with any
6 surgery, but the extent of that
7 response is significantly
8 different and short term.

9 BY MS. STUBBS:

10 Q. You also mentioned pelvic
11 pain and dyspareunia being risks that
12 were not contained in the IFU at the time
13 of Ms. Phillips' implant; correct?

14 A. Yes.

15 Q. Ms. Phillips had her implant
16 in 2005; correct?

17 A. Yes.

18 Q. And based on your review of
19 the records, are you aware that she
20 didn't go back to her implanting
21 physician for nearly eight years after
22 having that implant?

23 A. That's correct.

24 Q. And she hasn't had a pelvic

Konstantin Walmsley, M.D.

Page 49

1 exam since 2005 other than your exam; is
2 that correct?

3 A. Yes.

4 Q. In fact, her doctor, Dr.
5 Kim, suggested that she have a pelvic
6 exam and she refused; is that correct?

7 A. Yes.

8 Q. And so to date, you're the
9 only doctor that has performed a pelvic
10 exam on Ms. Phillips since she had the
11 implant; correct?

12 A. Yes.

13 Q. And when I deposed Ms.
14 Phillips, she represented to me that she
15 had dyspareunia post-implant on one
16 occasion. Did you see that in the
17 deposition?

18 A. I did.

19 Q. Have you seen anywhere in
20 the medical records where she complained
21 of dyspareunia post-implant on numerous
22 occasions?

23 MS. SANTRA: Object to form.

24 THE WITNESS: I did not see

Konstantin Walmsley, M.D.

Page 50

1 much reference to dyspareunia at
2 all, so I would have to answer
3 that question no.

4 BY MS. STUBBS:

5 Q. Did you see anywhere in the
6 medical records post-implant where Ms.
7 Phillips complained of pelvic pain?

8 MS. SANTRA: Object to form.

9 THE WITNESS: To some
10 degree, yes.

11 BY MS. STUBBS:

12 Q. Is that when she went to her
13 primary care doctor?

14 A. Well, I'm thinking about her
15 visit to Dr. Kim in 2012. I mean,
16 obviously, she came to see him requesting
17 the TVT device be removed. Although the
18 subject of pain wasn't answered or
19 explored, per se, she explained this
20 condition where she would be getting red
21 bumps, which to my mind is a presentation
22 of pain. I concluded that when she was
23 saying that, she was speaking about
24 pelvic pain. Now, I may not be correct

Konstantin Walmsley, M.D.

Page 51

1 in that, but that was my conclusion.

2 Q. Were the words "pelvic pain"
3 referenced in that visit at all?

4 A. Not to my recollection, no.

5 Q. And you familiarized
6 yourself with Dr. Kim's testimony in this
7 case; correct?

8 A. Yes.

9 Q. And are you aware that Dr.
10 Kim testified that if the words "pelvic
11 pain" or "dyspareunia" had been added to
12 the IFU in 2005, it wouldn't have changed
13 his decision to recommend TVT to this
14 plaintiff?

15 MS. SANTRA: Object to form.

16 THE WITNESS: I recall that.

17 BY MS. STUBBS:

18 Q. Would you agree that the
19 instructions for use or the IFU for a
20 product is only one source of risk
21 information available to a doctor?

22 A. I think it can be one of
23 several sources, yes.

24 Q. Would you agree that doctors

Konstantin Walmsley, M.D.

Page 52

1 rely on other sources of information when
2 gathering information about a product and
3 whether or not to use that product?

4 A. Yes.

5 Q. Do you personally, prior to
6 using a product, only rely on the IFU to
7 gain your risk information?

8 A. I rely heavily on the IFU.

9 Q. Do you rely on medical
10 literature?

11 A. I do.

12 Q. Do you rely on information
13 gathered through continuing medical
14 education seminars?

15 A. I do.

16 Q. Do you rely on information
17 discussed by your colleagues that use the
18 device?

19 A. Depending upon the
20 colleague, yes.

21 Q. Your second opinion, we've
22 talked briefly about, but that is the
23 alternative treatment that you are
24 proposing to Ms. Phillips. As opposed to

Konstantin Walmsley, M.D.

Page 53

1 having a TVT, you propose a fascial
2 sling; is that correct?

3 A. Yes.

4 Q. And you agreed earlier that
5 that is not an alternative device;
6 correct? That's using human tissue?

7 MS. SANTRA: Object to form.

8 THE WITNESS: Could you
9 repeat the question? I'm sorry.

10 MS. STUBBS: Sure.

11 BY MS. STUBBS:

12 Q. You would agree that that
13 alternative that you proposed does not
14 involve an alternative medical device.

15 A. No, it doesn't.

16 Q. It's a procedure; is that
17 correct?

18 A. Correct, yeah.

19 Q. Have you seen anywhere in
20 Ms. Phillips' records where any treating
21 physician has recommended that she have
22 her TVT taken out?

23 A. No.

24 Q. And based on her deposition,

Konstantin Walmsley, M.D.

Page 54

1 are you aware that she does not currently
2 have any treating physicians for her GYN
3 symptoms that she's complaining of?

4 A. Correct.

5 Q. And would you agree that no
6 doctor, in the medical records or Dr. Kim
7 in his deposition testimony, has opined
8 that the TVT device is in fact causing
9 the symptoms she's complaining of in this
10 lawsuit?

11 A. Correct.

12 Q. So one of your opinions, I
13 believe it's your last opinion, is that
14 she has a guarded prognosis; is that
15 correct?

16 A. Correct.

17 Q. What is your basis for that
18 opinion?

19 A. My basis for that opinion
20 stands on not only my review of the
21 medical records, depositions, but also on
22 my independent medical exam.

23 Q. Is it your recommendation
24 that Ms. Phillips have the TVT explanted?

Konstantin Walmsley, M.D.

Page 55

1 A. Possibly, yes.

2 Q. And what is your basis for
3 that?

4 A. Well, she currently has
5 pelvic pain. She currently has
6 dyspareunia, although she's only
7 attempted intimacy once since her sling
8 was placed.

9 There are other factors that
10 are contributing to her pelvic pain that
11 likely should be treated first in my
12 opinion --

13 Q. What are those factors?

14 A. Well, she has what I believe
15 is lichen sclerosus on the basis of some
16 inflammation on the posterior wall of her
17 vaginal space. In addition, she does
18 have some mild vulvovaginal atrophy. I
19 would recommend treating those
20 conditions, you know, in addition to
21 considering sling removal.

22 But if I can choose between
23 performing a procedure or trying
24 something medical or conservative, I'd

Konstantin Walmsley, M.D.

Page 56

1 probably opt on the medical/conservative
2 treatments first.

3 Q. And the lichen sclerosus and
4 the vaginal atrophy, are you contending
5 that those were caused by the mesh at
6 all?

7 A. I'm not.

8 Q. You also have the opinion
9 that Ms. Phillips has scar plate
10 formation as a result of the TVT; is that
11 correct?

12 A. Yes.

13 Q. When you examined Ms.
14 Phillips, did you see any evidence of any
15 erosion or extrusion of the mesh?

16 A. I did not.

17 Q. Have you seen anywhere in
18 the medical records where any doctor has
19 seen any erosion or extrusion of the
20 mesh?

21 A. No.

22 Q. When you state that there
23 was scar plate formation, describe for me
24 what you were able to palpate or see.

Konstantin Walmsley, M.D.

Page 57

1 A. So, visually, the tissue
2 around the sling appeared to be somewhat
3 thicker. On palpation, I could palpate
4 the ridge of scar tissue around the
5 sling. There was tenderness in the area
6 of the sling as I was examining this scar
7 tissue. There was no specific areas of
8 point tenderness.

9 Sometimes, in prior
10 examinations or with prior patients, they
11 might have areas that are more tender,
12 for example, up at the vaginal sulci
13 which are the upper corners of the
14 vaginal space. Ms. Phillips did not have
15 those findings.

16 Q. Ms. Phillips had had a
17 hysterectomy prior to having the TVT; is
18 that correct?

19 A. Yes.

20 Q. Would you agree that having
21 that type of surgery can also result in
22 scar formation?

23 MS. SANTRA: Object to form.

24 THE WITNESS: Possibly, yes.

Konstantin Walmsley, M.D.

Page 58

1 BY MS. STUBBS:

2 Q. Can it result in pelvic
3 pain?

4 A. Sometimes it can, yes.

5 Q. Can it result in
6 dyspareunia?

7 A. Yes.

8 Q. Ms. Phillips' TVT hasn't
9 been taken out in -- any portion of it;
10 correct? It's still intact in her body;
11 correct?

12 A. Yes.

13 Q. And so there's no pathology
14 in this case; is that correct?

15 A. There's not.

16 Q. And would you agree that
17 pathology would be necessary in order to
18 render an opinion to a reasonable degree
19 of medical certainty that the mesh in her
20 body had degraded?

21 A. For that particular finding,
22 yes.

23 Q. So did you see any evidence
24 of degradation?

Konstantin Walmsley, M.D.

Page 59

1 A. I did not.

2 Q. Did you see any evidence of
3 roping, curling, or fraying of the mesh
4 in Ms. Phillips?

5 A. I did not.

6 Q. Did you see any evidence of
7 shrinkage or contracture?

8 MS. SANTRA: Object to form.

9 THE WITNESS: Of the mesh,
10 you mean.

11 MS. STUBBS: Yes. I'm
12 sorry.

13 THE WITNESS: I did not.

14 BY MS. STUBBS:

15 Q. Did you see any evidence of
16 particle loss of the mesh in her body?

17 A. I did not.

18 Q. Did you see any evidence of
19 inadequate tissue ingrowth?

20 A. I did not.

21 Q. Did you see any evidence of
22 nerve entrapment?

23 MS. SANTRA: Object to form.

24 THE WITNESS: I did not.

Konstantin Walmsley, M.D.

Page 60

1 BY MS. STUBBS:

2 Q. I'd like to talk with you
3 now about Ms. Phillips' prior medical
4 history before having the TVT implanted
5 and then we'll talk about the actual
6 implant itself.

7 Would you agree that Ms.
8 Phillips suffered from back and hip pain
9 as a result of a motor vehicle accident
10 she had in the '90s and that pain
11 continued into the 2000's?

12 A. Yes.

13 Q. And after she had the
14 implant, she continued to see her primary
15 care doctor for pain related -- relating
16 back to that accident.

17 A. That's correct.

18 Q. Would you agree that she had
19 poorly controlled diabetes prior to
20 having the TVT implanted?

21 A. I mean, to some degree.

22 Q. And that worsened over time?

23 A. I think it's hard to really
24 track whether her diabetes was well

Konstantin Walmsley, M.D.

Page 61

1 controlled or poorly controlled because I
2 don't -- didn't recall seeing in her
3 medical records blood tests such as
4 hemoglobin A1Cs that would otherwise
5 point towards poorly controlled diabetes,
6 although there was mention made of poor
7 diabetic control by her primary care
8 doctor, Dr. Narula.

9 Q. Would you agree that Dr.
10 Narula's records reflect that Ms.
11 Phillips failed to comply on numerous
12 occasions with doctors' recommendations
13 regarding her care and treatment of her
14 diabetes?

15 MS. SANTRA: Object to form.

16 THE WITNESS: Comments to
17 that effect were made, yes.

18 BY MS. STUBBS:

19 Q. Ms. Phillips was also a
20 smoker; is that correct?

21 A. Yes.

22 Q. Would you agree that smoking
23 can impact wound healing following
24 surgery?

Konstantin Walmsley, M.D.

Page 62

1 A. Yes.

2 Q. Would you agree that smoking
3 has an impact on stress urinary
4 incontinence as a result of the constant
5 coughing, for example?

6 A. If one does have a constant
7 cough, that can certainly be a
8 predisposing factor for prolapse.
9 Whether or not it affects the surgical
10 management of stress urinary incontinence
11 is hard for me to opine on.

12 I mean, certainly after we
13 perform slings, we want patients to avoid
14 heavy lifting for a period of time, so if
15 you're heavily coughing during that
16 four-week interval, theoretically it
17 could create an opportunity for the sling
18 to move or the repair to be imperfect.

19 But usually after four
20 weeks, once a mesh sling is in place, it
21 doesn't really get affected by coughing,
22 sneezing, excess pressure, because it's
23 holding everything in place.

24 Q. Would you agree that Ms.

Konstantin Walmsley, M.D.

Page 63

1 Phillips' smoking history continued to
2 cause her health issues pre and
3 post-implant?

4 A. I mean, I certainly think
5 it's not a -- healthy to smoke, but it's
6 hard to quantify or for that matter
7 directly correlate her smoking with her
8 health between 2005 and 2016, for
9 example.

10 Q. Was she diagnosed with COPD?

11 A. I think she was.

12 Q. And I believe she saw her
13 primary care doctor on numerous occasions
14 for bronchitis and other upper
15 respiratory issues; correct?

16 A. Yes.

17 Q. And would you agree that
18 smoking can contribute to those types of
19 health issues?

20 A. Yes.

21 Q. Did you see in the records
22 where her doctor, Dr. Narula, repeatedly
23 cautioned her to quit smoking?

24 A. Yes.

Konstantin Walmsley, M.D.

Page 64

1 Q. And she refused that advice;
2 is that correct?

3 MS. SANTRA: Object to form.

4 THE WITNESS: I'm not sure
5 if she refused the advice, but she
6 certainly didn't abide by it.

7 MS. STUBBS: Okay. That's
8 fair.

9 THE WITNESS: Yeah.

10 BY MS. STUBBS:

11 Q. It looks like Ms. Phillips
12 first presented to Dr. Kim in October of
13 2004; is that correct?

14 A. Yes.

15 Q. And when she presented, she
16 had mixed incontinence; correct?

17 A. Primarily stress, but with
18 some urge incontinence, yes.

19 Q. And that's when he
20 prescribed the Detrol; correct?

21 A. Yes.

22 Q. And we talked about earlier
23 how she improved for a period of time,
24 but then decided to go forward with the

Konstantin Walmsley, M.D.

Page 65

1 implant for her stress incontinence;
2 correct?

3 A. Yes.

4 Q. Did you see in the records
5 where apparently there was a surgery
6 scheduled to do the TVT and then the
7 plaintiff wanted to move it up to January
8 as opposed to March?

9 A. I do recall seeing that,
10 yes.

11 Q. And, ultimately, that
12 surgery was performed on January 10th,
13 2005; correct?

14 A. Yes.

15 Q. Did you see any evidence of
16 any complications as a result of that
17 surgery?

18 A. No, I did not.

19 Q. And a cystoscopy was
20 performed at the time of the implant;
21 correct?

22 A. Yes.

23 Q. Did you see any evidence of
24 injury to the bladder or urethra as a

Konstantin Walmsley, M.D.

Page 66

1 result of that implant?

2 A. I did not.

3 Q. And was she discharged the
4 same day as the procedure?

5 A. She was.

6 Q. Would you agree that the TVT
7 implant is a minimally invasive
8 procedure?

9 A. Correct.

10 MS. STUBBS: I'd like to
11 look at the operative report for
12 her implant and I'll mark it as
13 Exhibit 8.

14 - - -

15 (Deposition Exhibit No.
16 Walmsley (Phillips)-8, 1/10/05
17 Operative Report for Joanne M.
18 Phillips, PHILLIPSJ_UTMC_MDR00021
19 through PHILLIPSJ_UTMC_MDR00023,
20 was marked for identification.)

21 - - -

22 BY MS. STUBBS:

23 Q. If you would go with me to
24 "Operative Indications," please, it

Konstantin Walmsley, M.D.

Page 67

1 states: "The patient is a 51 year old
2 lady with significant stress urinary
3 incontinence"; correct?

4 A. Yes.

5 Q. And would you agree that TVT
6 at the time it was implanted in Ms.
7 Phillips was an appropriate device for
8 treatment of significant stress urinary
9 incontinence?

10 A. Yes.

11 Q. And then next it states,
12 "The risks and benefits of transvaginal
13 tape sling including bleeding, infection,
14 retention, injury to adjacent organs,
15 erosion, and anesthesia related
16 complications were discussed, and she
17 agrees to proceed"; correct?

18 A. Yes.

19 Q. And after having the TVT
20 implanted, Ms. Phillips didn't attend her
21 follow-up appointment in February;
22 correct?

23 A. That's correct.

24 Q. And she was sent a letter by

Konstantin Walmsley, M.D.

Page 68

1 Dr. Kim letting her know that she had
2 missed her appointment, and she didn't go
3 back to him until 2012; is that correct?

4 A. Yes.

5 Q. However, she did go see her
6 primary care doctor in between the 2005
7 implant and 2012, when she returned to
8 Dr. Kim; correct?

9 A. Yes.

10 Q. Would you agree that the
11 visits that -- with her primary care
12 doctor between 2005 following the implant
13 and 2012 before she goes back to Dr. Kim
14 -- that the bulk of those visits related
15 to health issues regarding her poorly
16 controlled diabetes and her lower back
17 pain as a result of her motor vehicle
18 accident?

19 MS. SANTRA: Object to form.

20 That's a large body of records.

21 If you want to show him a few --

22 MS. STUBBS: Sure.

23 I'll mark as Exhibit 9 the
24 records immediately prior and then

Konstantin Walmsley, M.D.

Page 69

1 following the implant with her
2 primary care doctor.

3 - - -

4 (Deposition Exhibit No.
5 Walmsley (Phillips)-9, Twenty
6 Pages of Medical Records Beginning
7 with 12/13/05 Visit to Dr. Narula,
8 PHILLIPSJ_LAFHC_MDR00056, was
9 marked for identification.)

10 - - -

11 BY MS. STUBBS:

12 Q. So the first record is dated
13 12/13/05. Do you see that?

14 A. I do.

15 Q. And it says she has
16 occasional pain in her lower back, but no
17 frequency or dysuria; correct?

18 A. Yes.

19 Q. And she's having pain in her
20 lower abdomen where the scar was; is that
21 correct?

22 A. From her recent sling, yes.

23 Q. Would you turn to the next
24 record, please?

Konstantin Walmsley, M.D.

Page 70

1 A. Yes.

2 Q. On this record, she is
3 reporting pain in her lower back on
4 external rotation of both hips.

5 Do you see that?

6 A. Yes.

7 Q. And she -- those injuries
8 related to the motor vehicle accident she
9 had had back in the '90s; correct?

10 A. I would assume so, yes.

11 Q. She injured her hips in that
12 accident; correct?

13 A. Yes.

14 Q. Do you also see where it
15 says in the first paragraph, "is in total
16 denial in terms of her blood sugar and
17 blood pressure control"?

18 A. I do see that.

19 Q. Would you turn with me until
20 you get -- I'm sorry. The Bates numbers
21 are cut off for some reason, but if you
22 keep going until we get to 7/16/08 --
23 it's a few more pages. You'll see it at
24 the top.

Konstantin Walmsley, M.D.

Page 71

1 A. I'm there.

2 Q. Okay -- this record, it
3 says, "She is staying nervous and
4 stressed. She has to watch the grand
5 kids. Her blood pressure is under fair
6 control. Her blood sugars are running
7 high. Her back, legs, and feet hurt.
8 She says that it is from diabetes. She
9 does not want to go on insulin. No
10 abdominal pain, nausea, fever"; correct?

11 A. Correct.

12 Q. So up until this point, has
13 she complained to the -- the one doctor
14 she was seeing, Dr. Narula, of any
15 dyspareunia? And take your time to look
16 at it.

17 A. To date, Dr. Narula's
18 records have no specific language about
19 dyspareunia in them.

20 Q. What about any reference to
21 pelvic pain?

22 (Pause.)

23 THE WITNESS: I don't see
24 any references to pelvic pain thus

Konstantin Walmsley, M.D.

Page 72

1 far.

2 BY MS. STUBBS:

3 Q. The next record is dated
4 9/4/08. Do you see that?

5 A. I do.

6 Q. "Patient has cough,
7 wheezing, sinus drainage. No abdominal
8 pain, nausea. Her back continues to
9 hurt. She has had it since her motor
10 vehicle accident when she was 23 years of
11 age. Her hips became crooked at that
12 time. No numbness, tingling, weakness.
13 Hurts to sit or stand on it for a long
14 period of time. No abdominal pain."

15 So up until this point, Ms.
16 Phillips is complaining of pain related
17 to her motor vehicle accident injuries;
18 correct?

19 A. Yes.

20 Q. Have you seen any reference
21 up until this date, 9/4/08, of any
22 complaints relating to her TVT implant
23 other than the 12/05 one where she talks
24 about the scar area hurting?

Konstantin Walmsley, M.D.

Page 73

1 A. I have not.

2 Q. Would you turn several pages
3 until you get to 11/3/10?

4 (Pause.)

5 THE WITNESS: Okay.

6 BY MS. STUBBS:

7 Q. On this visit, she's again
8 complaining of lower back pain; correct?

9 A. Yes.

10 Q. And based on your review of
11 her records, she had lower back pain as a
12 result of her motor vehicle accident;
13 correct?

14 A. In part, yes.

15 Q. What else do you think
16 contributed to that lower back pain?

17 A. I mean, it's such a broad
18 diagnostic category, low back pain; that
19 I'm sure a big part of her low back pain
20 relates to her motor vehicle accident and
21 even Dr. Narula's medical documentation
22 speaks to that.

23 You know, that being said,
24 she may also have additional causes of

Konstantin Walmsley, M.D.

Page 74

1 low back pain, whether it be arthritis or
2 things of that nature.

3 Q. Do you in any way believe
4 her lower back pain was caused by the TVT
5 implant?

6 A. I don't.

7 Q. And she was diagnosed with
8 degenerative arthritis on this visit;
9 correct?

10 A. Correct.

11 Q. If you would go to the last
12 visit, it's the last page, 10/24/11, so
13 this is the year before she goes back to
14 Dr. Kim; correct?

15 A. Yes.

16 Q. And it says, "The patient
17 describes pain in both knees and lower
18 back. Her nerves are shot. She had a
19 car accident today. No abdominal pain,
20 change in appetite, weight or fever";
21 correct?

22 A. Yes.

23 Q. So, again, the year before
24 she returns to Dr. Kim, she doesn't have

Konstantin Walmsley, M.D.

Page 75

1 any GYN complaints; correct?

2 MS. SANTRA: Object to form.

3 THE WITNESS: She doesn't

4 voice any, no.

5 BY MS. STUBBS:

6 Q. And she doesn't have any

7 abdominal pain based on this record;

8 correct?

9 A. She doesn't voice any, no.

10 Q. When Ms. Phillips went back

11 to Dr. Kim, I believe it was -- September

12 of 2012; correct?

13 A. I thought it was October of

14 2012.

15 Q. 10/10/12; is that right?

16 A. Correct.

17 Q. -- that was the first visit

18 she had had with him since the implant;

19 correct?

20 A. Yes.

21 Q. And she approached Dr. Kim

22 about wanting the TVT implant out; is

23 that correct?

24 A. Yes.

Konstantin Walmsley, M.D.

Page 76

1 Q. Were you aware of whether or
2 not she had filed a lawsuit at that time?

3 A. I was not. I am not.

4 Q. Have you seen anywhere in
5 the medical records prior to the visit on
6 10/10/12 where any doctor recommended
7 that she have the TVT implant out?

8 A. No.

9 Q. And have you seen anywhere
10 in the medical records prior to 10/10/12
11 where any doctor conducted a pelvic exam?

12 A. No.

13 Q. And have you seen anywhere
14 in the medical records prior to 10/10/12
15 where any doctor noted pelvic pain or
16 dyspareunia?

17 A. Obviously with the exception
18 of that one visit in December 12th where
19 she had probably more retropubic, but
20 nonetheless pelvic pain, no, and no for
21 dyspareunia either.

22 Q. And Dr. Kim noted that he
23 did not believe the TVT was causing her
24 problems at that time; is that correct?

Konstantin Walmsley, M.D.

Page 77

1 A. He did make that comment.

2 Q. And he suggests that she get
3 a second opinion; is that right?

4 A. Correct.

5 Q. And did she ever get that
6 second opinion?

7 A. No.

8 Q. And did she ever have a
9 pelvic exam after that visit?

10 A. Not until I saw her.

11 Q. Other than the IME. Thank
12 you.

13 I'd like to talk now about
14 your IME. Can you walk me through the
15 procedure? So from the time the patient,
16 Ms. Phillips, comes into your office, up
17 until the end of the exam, what's the
18 procedure you underwent to perform your
19 IME?

20 A. Certainly. So typically
21 what would happen and what Ms. Phillips
22 did is, she presents herself to the
23 office. There is some paperwork that's
24 filled out, questions about past medical

Konstantin Walmsley, M.D.

Page 78

1 history, questions about medications,
2 questions about current complaints.
3 There is a review of systems form that
4 the patient fills out.

5 Once those forms are filled
6 out, she comes back to an examination
7 room where one of my medical assistants
8 enters all of the data into the
9 electronic health record template for her
10 visit.

11 Once that's completed, then
12 I will come into the examination room,
13 introduce myself to the patient, and ask
14 them questions relating to their
15 particular complaint.

16 In the case of Mrs.
17 Phillips, if you go to page 2 of my IME,
18 you'll see that my history of physical
19 illness -- or history of present illness,
20 excuse me -- we call that the HPI, that
21 in essence is 16 lines long and it is a
22 memorialization of the patient's
23 complaints, which in some part are also
24 predicated on the questions I'm asking

Konstantin Walmsley, M.D.

Page 79

1 the patient.

2 Once I complete that
3 history-taking, during which time I
4 review her problems, her chief
5 complaints, medications, allergies, past
6 medical and past surgical history, social
7 and family history, and review of
8 systems, then I'll leave the room and in
9 this case have the patient change.
10 They'll cover -- they'll take their
11 clothes off from the waist down, cover
12 themselves with a drape. I step out of
13 the room during this process and then
14 come back in the room with a female
15 chaperone to examine the patient.

16 My examination is a
17 comprehensive examination. I exam their
18 heart, lungs, abdomen, back, skin. When
19 I do the pelvic exam, in addition to
20 doing a pelvic exam, I occasionally will
21 scan the bladder. If there's a question
22 of incomplete emptying, I'll do that --
23 in Ms. Phillips' case, I did -- and then
24 I'll perform a complete pelvic exam,

Konstantin Walmsley, M.D.

Page 80

1 after which time, I go to my office,
2 record the physical exam findings, and
3 then finish the office visit with the
4 patient coming to my office.

5 It's a little bit of a
6 nuance in the IME world because I'm not a
7 treating physician, so I'm not
8 necessarily going to engage the patient
9 in treatment, but I will discuss with the
10 patient my conclusions, and that's what I
11 did with Ms. Phillips.

12 Q. You indicated you did do a
13 bladder scan; is that correct?

14 A. I did.

15 Q. Did you see any evidence of
16 incomplete emptying?

17 A. Her postvoid residual was 32
18 milliliters, which is fairly low.

19 Q. You mentioned some intake
20 forms --

21 A. Yes.

22 Q. -- is that something --
23 Hayleigh, do you all have those or --

24 MS. SANTRA: I don't think

Konstantin Walmsley, M.D.

Page 81

1 we've gotten those.

2 THE WITNESS: Typically what
3 happens with the intake forms is,
4 once the data is entered, they're
5 shredded.

6 MS. STUBBS: Will you all
7 just check on that -- if you don't
8 have them, fine. If you do, will
9 you give them to counsel?

10 THE WITNESS: Sure.

11 MS. STUBBS: Okay.

12 BY MS. STUBBS:

13 Q. Let's turn to the second
14 page of your IME. Let's start with
15 social history. Under "Smoking Status,"
16 it says, "Unknown if ever smoked."

17 Would you agree based on
18 your review now of her records that she
19 was a smoker?

20 A. Yes.

21 Q. And then "History of Present
22 Illness," I want to talk about where
23 she's -- is this based on what she's
24 telling you about her symptoms or your

Konstantin Walmsley, M.D.

Page 82

1 nurse?

2 A. No, no.

3 Q. It's you?

4 A. It's me asking her questions
5 and her responding to my questions.

6 Q. Do you see where it says,
7 "developed pain shortly thereafter"?

8 A. Yes.

9 Q. And that's after her TVT
10 implant; correct?

11 A. Correct.

12 Q. And then it says, "had some
13 vaginal bleeding on and off for six
14 months"; is that correct?

15 A. Yes.

16 Q. Did you see anywhere in the
17 medical records where she reported pain
18 or vaginal bleeding after having the TVT
19 implanted?

20 A. Well, firstly, when she saw
21 her primary care doctor in December of
22 2005, there was some pain in the area of
23 her incisions from her TVT.

24 With regards to pelvic pain,

Konstantin Walmsley, M.D.

Page 83

1 I didn't see any record of that
2 thereafter, but obviously she has other
3 sources of pain that she did complain
4 about afterwards.

5 Q. What about vaginal bleeding?

6 A. I don't recall seeing that.

7 Q. And it looks like after 18
8 months, she started developing MUI. Is
9 that mixed urinary incontinence?

10 A. Correct.

11 Q. And that would be stress and
12 urge; correct?

13 A. Yes.

14 Q. So the urge incontinence
15 that had gotten better on Detrol came
16 back after having the TVT implant; is
17 that correct?

18 A. Yes.

19 MS. SANTRA: Object to form.

20 BY MS. STUBBS:

21 Q. And would you agree that TVT
22 is not indicated to treat urge?

23 A. It's not indicated to treat
24 urge.

Konstantin Walmsley, M.D.

Page 84

1 Q. And then it says, "After
2 about 1 year, she started developing
3 pelvic pain. She also had dyspareunia,
4 as she was sexually active with her
5 husband for several years (till 2009)."

6 Based on my deposition of
7 plaintiff, would you agree that she
8 stated on the record that she only had
9 sex one time after the implant?

10 MS. SANTRA: I have that
11 deposition if --

12 THE WITNESS: I have it
13 right here, actually.

14 (Pause.)

15 THE WITNESS: Yes, one time.

16 BY MS. STUBBS:

17 Q. And she did note to you that
18 she had had some mild discomfort with
19 intercourse prior to having the TVT;
20 correct? That's what's reflected. It
21 says, "She had some mild discomfort with
22 intimacy before surgery but this was much
23 worse"; is that correct?

24 A. Correct, yes.

Konstantin Walmsley, M.D.

Page 85

1 Q. And then it says, "She
2 describes a rough, tearing sensation to
3 sex especially upon entering the vagina."

4 A. Right.

5 Q. Did you see anywhere in the
6 medical records where anything of that
7 nature was mentioned to any of her
8 treating physicians following the TVT
9 implant?

10 A. I did not.

11 Q. You also note a history of
12 two to three UTIs a month. Did you see
13 anywhere in the medical records where
14 that was indicated?

15 A. I did not.

16 Q. Did you see any evidence of
17 a urinary tract infection upon your
18 examination?

19 A. No.

20 Q. And you saw no erosion or
21 extrusion; correct?

22 A. I did not.

23 Q. And when you were able to --
24 when you noted tenderness upon your exam,

Konstantin Walmsley, M.D.

Page 86

1 was that at the site of where the mesh
2 was located?

3 A. Yes.

4 Q. Did you see any evidence of
5 where Ms. Phillips went back to Dr. Kim
6 after the 10/10/12 visit?

7 A. I don't believe so.

8 Q. Did you see any evidence
9 where she saw any urogynecologist,
10 gynecologist, or urologist after
11 10/10/12, other than your IME?

12 A. No.

13 Q. And so you performed a
14 pelvic exam; correct?

15 A. Yes.

16 Q. And you took your -- did
17 your do a urinalysis as well?

18 A. A urine analysis?

19 Q. Yes.

20 A. Yes.

21 Q. And you did a bladder scan;
22 correct?

23 A. Yes.

24 Q. Any other testing or exams

Konstantin Walmsley, M.D.

Page 87

1 that you performed at that time on her
2 female anatomy?

3 A. No, ma'am.

4 Q. Did she report any bowel
5 problems to you during her IME?

6 A. Yes.

7 Q. What are those?

8 A. She noted that she had some
9 constipation.

10 Q. Is it your opinion that that
11 constipation is related to the mesh?

12 A. No.

13 Q. Do you have an opinion as to
14 what the cause of her constipation is?

15 A. Not specifically, I don't.

16 Q. Have we discussed all of
17 your opinions to date during this
18 deposition today?

19 MS. SANTRA: Object to form.

20 THE WITNESS: I believe so,
21 yes.

22 MS. STUBBS: I don't have
23 any further questions, Hayleigh.
24 Do you?

Konstantin Walmsley, M.D.

Page 88

1 MS. SANTRA: Okay. I'm
2 going to, but I -- is it okay if I
3 go to the bathroom real quick?

4 MS. STUBBS: Of course.
5 We'll go off the record.

6 (A recess was taken from
7 2:02 p.m. to 2:06 p.m.)

8 - - -

9 EXAMINATION

10 - - -

11 BY MS. SANTRA:

12 Q. Dr. Walmsley, you performed
13 a differential diagnosis when coming to
14 your opinions about Ms. Phillips;
15 correct?

16 A. I did.

17 Q. And your opinions that
18 you've expressed about Ms. Phillips are
19 based on your clinical experience, your
20 review of her medical records, your
21 independent examination of Ms. Phillips,
22 and your knowledge of the medical
23 literature; is that right?

24 A. Correct.

Konstantin Walmsley, M.D.

Page 89

1 Q. And when you were performing
2 your differential diagnosis for Ms.
3 Phillips, did you take into account all
4 of her other medical conditions,
5 including diabetes, smoking, the hip and
6 back pain from her motor vehicle accident
7 in the 1990s, her abdominal hysterectomy,
8 her appendectomy, tumor removals from her
9 neck, her COPD, hypertension, arthritis,
10 GERD, and hyperlipidemia?

11 MS. STUBBS: Object to form.

12 THE WITNESS: Yes.

13 BY MS. SANTRA:

14 Q. And is it -- based on your
15 differential diagnosis, is it your
16 opinion that the TVT sling is a
17 substantial factor in the pain that you
18 palpated upon examination?

19 A. Yes.

20 MS. STUBBS: Object to form.

21 BY MS. SANTRA:

22 Q. And how did you rule out Ms.
23 Phillips' hysterectomy as a cause for
24 that pain that you observed upon

Konstantin Walmsley, M.D.

Page 90

1 examination?

2 A. Well, I mean, first off, her
3 hysterectomy was performed over 20 years
4 ago and, generally speaking, if one
5 encounters pelvic pain or dyspareunia
6 from a procedure such as a hysterectomy,
7 you would expect that that would be
8 present soon after the hysterectomy and
9 certainly a chronic condition that's
10 commented on in the medical records. I
11 mean, she had no comment made as to that
12 being the case in the medical records
13 that I reviewed.

14 In addition, at least on
15 physical examination, when I examined Ms.
16 Phillips, she had no tenderness at the
17 apex of the vagina, which is typically
18 where one encounters pelvic pain after a
19 hysterectomy.

20 Q. In your case-specific
21 opinions, you mention the scar plate
22 formation that you saw that was due to
23 the TVT sling; is that right?

24 A. Yes.

Konstantin Walmsley, M.D.

Page 91

1 Q. And is that scar plate
2 formation that you -- that was painful
3 for Ms. Phillips when you examined her,
4 is that evidence of her foreign body
5 reaction to the sling?

6 A. That's correct.

7 Q. And you talked about lichen
8 sclerosus and vaginal atrophy; is that
9 correct?

10 A. I did, yes.

11 Q. And Ms. Phillips has those
12 conditions as well?

13 A. Yes, she has evidence of
14 both of those conditions.

15 Q. Even given those conditions,
16 is the TVT -- excuse me. Strike that.

17 Even given her lichen
18 sclerosus and vaginal atrophy, is the TVT
19 sling still a substantial factor in
20 producing the pain that you reproduced
21 upon examination?

22 MS. STUBBS: Object to form.

23 THE WITNESS: Yes.

24 BY MS. SANTRA:

Konstantin Walmsley, M.D.

Page 92

1 Q. I want to talk about your
2 reliance list for a minute. In your
3 reliance list, you say that you
4 incorporated Dr. Blaivas' general TVT
5 causation report; is that correct?

6 A. Not as specifically as you
7 just stated, but, yes, I did rely upon
8 Dr. Blaivas' report for general opinions.

9 Q. And so before writing your
10 report for Ms. Phillips, you had reviewed
11 Dr. Blaivas' general causation report on
12 the TVT?

13 A. Yes.

14 Q. And to the extent Dr.
15 Blaivas relied on Ethicon internal
16 documents or other materials that he
17 cites in his report, you would
18 incorporate all of that into your -- part
19 of your -- or all of Dr. Blaivas'
20 conclusions from his review of those
21 documents into your knowledge base; is
22 that correct?

23 MS. STUBBS: Object to form.

24 MS. SANTRA: I don't know if

Konstantin Walmsley, M.D.

Page 93

1 I need to ask that again.

2 THE WITNESS: Well, I think
3 to answer your question, I didn't
4 specifically review Ethicon
5 internal documents myself relating
6 to this case.

7 Obviously having read and
8 reviewed Dr. Blaivas' report,
9 which certainly does reflect his
10 review of those internal
11 documents, what I can tell you is,
12 having trained under Dr. Blaivas
13 and knowing his reputation as a
14 key opinion leader in the field of
15 urology and the management of
16 incontinence in both men and
17 women, I would trust and rely on
18 his opinion -- you know, on his
19 interpretation of those documents
20 and records.

21 BY MS. SANTRA:

22 Q. And I believe you mentioned
23 the fact that the TVT IFU in 2005 did not
24 have dyspareunia or chronic pain as some

Konstantin Walmsley, M.D.

Page 94

1 of the adverse events; is that correct?

2 A. Yes.

3 Q. And the 2015 TVT IFU does
4 list dyspareunia and chronic pain as
5 potential adverse events; is that
6 correct?

7 MS. STUBBS: Object to the
8 form.

9 THE WITNESS: Amongst other
10 potential adverse events, yes.

11 BY MS. SANTRA:

12 Q. So even according to
13 Ethicon, the TVT can cause chronic pain
14 and dyspareunia; correct?

15 MS. STUBBS: Object to the
16 form.

17 THE WITNESS: That's
18 correct.

19 BY MS. SANTRA:

20 Q. You were asked some
21 questions about -- some questions
22 comparing an autologous sling to the TVT
23 mesh device. Do you remember those
24 questions?

Konstantin Walmsley, M.D.

Page 95

1 A. I do.

2 Q. And I think you were asked
3 generally whether an autologous sling can
4 cause dyspareunia or pelvic pain. Do you
5 remember that question?

6 A. I do.

7 Q. Is there a difference in the
8 characteristic and nature of any
9 dyspareunia or pelvic pain that's caused
10 by an autologous sling versus the nature
11 and characteristic of dyspareunia or
12 pelvic pain caused by a mesh device?

13 MS. STUBBS: Object to the
14 form.

15 THE WITNESS: Yes.

16 BY MS. SANTRA:

17 Q. What are some of the
18 differences?

19 A. So using an autologous
20 fascial sling as compared to synthetic
21 mesh creates a different host response.
22 When using mesh in the pelvic arena,
23 there is an inflammatory response that
24 tends to generate more scarring and

Konstantin Walmsley, M.D.

Page 96

1 fibrosis and more inflammation, which
2 tends to lead towards more significant
3 dyspareunia and pelvic pain, not only
4 with regards to intensity of the pain,
5 but chronicity of the pain.

6 Autologous facial slings can
7 create or have these adverse events as
8 well. It's part of the informed consent
9 process for autologous facial slings.
10 However, the nature of the pain and the
11 nature of the dyspareunia, both
12 quantitatively and qualitatively are
13 different because the inflammatory
14 response, that response which can create
15 fibrosis and scarring, is much less
16 intense and less significant than what is
17 seen with synthetic mesh.

18 One of the reasons you need
19 to suture an autologous fascial sling in
20 place, for example, is because unlike
21 synthetic mesh, where the fibrosis and
22 scarring essentially sets that mesh in
23 place, fairly quickly, with autologous
24 facial slings, that type of vigorous

Konstantin Walmsley, M.D.

Page 97

1 inflammatory response is essentially
2 absent such that if you were to place an
3 autologous fascial sling and not stitch
4 it into location, it would have a very
5 high rate of migration and failure
6 because it wasn't -- it wouldn't position
7 itself under the urethra in such a way as
8 to create support effectively.

9 Q. In regards to Exhibit 7,
10 which is the AUGS and SUFU statement that
11 we -- that defense counsel went over --

12 A. Yes.

13 Q. -- have you seen that
14 statement before?

15 A. I have.

16 Q. And does anything in that
17 statement change your opinions today
18 about Ms. Phillips?

19 A. No.

20 Q. And defense counsel asked
21 you questions to the effect of that the
22 IFU is just one source of information for
23 doctors; is that correct?

24 A. I remember that question,

Konstantin Walmsley, M.D.

Page 98

1 yes.

2 Q. And you said that you rely
3 heavily on IFUs for your practice?

4 A. I do.

5 Q. Can you explain that a
6 little bit?

7 A. I can.

8 There's no question that
9 gaining experience and knowledge with
10 procedures, other than on a personal
11 level, can be augmented by research and
12 review; and inasmuch as some of that
13 review can be related to peer-reviewed
14 literature, can be related to published
15 guidelines, can be related to opinions
16 shared by key opinion leaders or
17 colleagues, to my mind, the framework of
18 knowledge, whether it's a package insert
19 for a medication, for example, or an IFU
20 for a medical device is -- the
21 foundation, I should say, really are
22 those types of products in my practice.

23 I believe that the IFU
24 serves as a guide for literature, for

Konstantin Walmsley, M.D.

Page 99

1 opinions put forth by national leaders in
2 fields such as incontinence; and to some
3 degree, if the IFU is incomplete, the
4 literature is incomplete, the opinions
5 put forth by key opinion leaders are
6 incomplete because these very -- these
7 very authors, these very surgeons -- the
8 literature that even in my reliance list
9 is to some degree premised on information
10 in package inserts and IFUs, for example.

11 Q. And that would be kind of
12 especially true when a product is in the
13 first few years of a product being on the
14 market; is that right?

15 MS. STUBBS: Object to the
16 form.

17 THE WITNESS: To some
18 extent, I think that's when the
19 IFU is the most critically
20 important, because that's really
21 setting the foundation for how you
22 want to incorporate the use of a
23 medical device in your practice.

24 BY MS. SANTRA:

Konstantin Walmsley, M.D.

Page 100

1 Q. Counsel asked you some
2 questions about whether in every report
3 you've written, you found that the TVT
4 was a cause for the plaintiff's injuries.

5 Do you remember that line of
6 questioning?

7 A. I remember some questioning
8 regarding IFU commentary.

9 Q. And for the TVT, that IFU
10 wasn't changed in any substantial way
11 until 2015; is that correct?

12 MS. STUBBS: Object to the
13 form.

14 THE WITNESS: Yes, it is.

15 BY MS. SANTRA:

16 Q. So from 2000 to 2015, when
17 it was substantially changed, there was
18 basically the same information in the TVT
19 IFU; correct?

20 MS. STUBBS: Objection to
21 form.

22 THE WITNESS: Essentially,
23 yes.

24 BY MS. SANTRA:

Konstantin Walmsley, M.D.

Page 101

1 Q. Have you rendered all your
2 opinions to a reasonable degree of
3 medical certainty?

4 A. I have, yes.

5 MS. SANTRA: I think that is
6 all I have for you.

7 MS. STUBBS: I don't have
8 any further questions.

9 (Witness excused.)

10 (Deposition concluded at
11 approximately 2:23 p.m.)

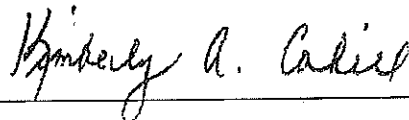
12
13
14
15
16
17
18
19
20
21
22
23
24

Konstantin Walmsley, M.D.

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, KONSTANTIN WALMSLEY, M.D., have the opportunity to read and sign the deposition transcript.



KIMBERLY A. CAHILL, a
Federally Approved Registered
Merit Reporter and Notary Public
Dated: August 22, 2016

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

Konstantin Walmsley, M.D.

Page 103

1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

21

22

23

24

Konstantin Walmsley, M.D.

Page 104

1

- - - - -

E R R A T A

2

- - - - -

3

4

PAGE LINE CHANGE

5

6

REASON:

7

8

REASON:

9

10

REASON:

11

12

REASON:

13

14

REASON:

15

16

REASON:

17

18

REASON:

19

20

REASON:

21

22

REASON:

23

24

REASON:

Konstantin Walmsley, M.D.

Page 105

1

2

ACKNOWLEDGMENT OF DEPONENT

3

4

I, _____, do

5

hereby certify that I have read the

6

foregoing pages, 1 - 106, and that the

7

same is a correct transcription of the

8

answers given by me to the questions

9

therein propounded, except for the

10

corrections or changes in form or

11

substance, if any, noted in the attached

12

Errata Sheet.

13

14

15

16

KONSTANTIN WALMSLEY, M.D.

DATE

17

18

19

Subscribed and sworn

to before me this

20

_____ day of _____, 20____.

21

My commission expires: _____

22

23

Notary Public

24

Konstantin Walmsley, M.D.

Page 106

1	LAWYER'S NOTES		
2	PAGE	LINE	
3	_____	_____	_____
4	_____	_____	_____
5	_____	_____	_____
6	_____	_____	_____
7	_____	_____	_____
8	_____	_____	_____
9	_____	_____	_____
10	_____	_____	_____
11	_____	_____	_____
12	_____	_____	_____
13	_____	_____	_____
14	_____	_____	_____
15	_____	_____	_____
16	_____	_____	_____
17	_____	_____	_____
18	_____	_____	_____
19	_____	_____	_____
20	_____	_____	_____
21	_____	_____	_____
22	_____	_____	_____
23	_____	_____	_____
24	_____	_____	_____